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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,127	10/05/2005	Petra Cirpus	12810-00136-US	6201

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EXAMINER	
MCELWAIN, ELIZABETH F	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
11/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,127	CIRPUS ET AL.	
	Examiner	Art Unit	
	Elizabeth F. McElwain	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *4 and 17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-16* is/are rejected.

7)☒ Claim(s) *21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed August 13, 2008 has been entered.

Claims 1-3 and 5-16 are currently amended.

Claim 21 is newly submitted.

Claims 1-21 are pending.

Election/Restrictions

1. This application contains claims 4 and 17-20 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

2. Claims 1-3, 5-16 and 21 are drawn to the elected invention and are examined on the merits.

Claim Rejections - 35 USC § 112

The rejections of the claims under 35 USC 112-2nd are withdrawn in view of the amendment of the claims.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3 and 5-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid sequence encoding SEQ ID NO: 2, or for an isolated nucleic acid sequence encoding a polypeptide having at least 95% homology

with SEQ ID NO: 2 **and** having delta-4 desaturase activity, and being enabling for a transgenic yeast or plant transformed therewith and a process of producing polyunsaturated fatty acids by transforming yeast or plants with a construct comprising SEQ ID NO: 2, does not reasonably provide enablement for any nucleic acid sequence that has at least 95% homology with SEQ ID NO: 2 without a designated functional activity, and does not provide enablement for any gene construct comprising said sequence and a multitude of other genes for fatty acid biosynthesis or lipid metabolism, and for any nonhuman organism transformed with any of said sequences, and for producing polyunsaturated fatty acids with any of said sequences and in any nonhuman organism. It is noted that claims 1-3 and 5-16 no longer limit the claims to nucleic acid sequences that encode a polypeptide with delta-4 desaturase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

5. The claims are drawn to a nucleic acid encoding a polypeptide having at least 95% homology at the amino acid level with SEQ ID NO: 2. Claims also encompass said nucleic acid sequence in a vector and a transgenic nonhuman organism comprising said sequence and a process of producing polyunsaturated fatty acids by culturing the transgenic organism. However, the specification only exemplifies a nucleic acid encoding SEQ ID NO: 2 transformed into yeast that are fed with DPA for the production of polyunsaturated fatty acids, such as DHA, wherein SEQ ID NO: 2 has delta-4 desaturase activity. The specification discusses how to transform a plant, but no plants are exemplified and no results with regard to fatty acid production are provided.

6. The specification teaches that the delta-4 desaturase from Euglena that is disclosed as SEQ ID NO: 2 is specific for conversion of DPA to DHA, and that the double bond at the C4-C5 position is only introduced when a double bond is already present at the C7-C8 position. Therefore, the specification teaches that DPA must be present for use of the claimed delta-4 desaturase coding sequence. While the specification teaches transformed yeast that are grown in media supplemented with DPA, the specification does not teach any other organisms in which the claimed delta-4 desaturase will function or the culture conditions required for use of the claimed nucleic acid to produce polyunsaturated fatty acids. Nor does the specification teach how to use the claimed constructs comprising one or more nucleic acids encoding a polypeptide having at least 95% homology at the amino acid level with SEQ ID NO: 2 and further comprising any unspecified number of fatty acid biosynthetic genes or lipid metabolism genes that are listed in claims 6 or 7, wherein there is no limitation that the polypeptide have delta-4 desaturase activity.

7. Given the recognition that use of the nucleic acid of the present invention is dependent on the presence of the appropriate fatty acid intermediates in an organism or culture medium, as discussed in the specification; and given the lack of guidance in the specification for use of sequences other than SEQ ID NO: 2 in organisms other than yeast cultured with DPA; and the absence of other working examples; and given the breadth of the claims, which encompass any nucleic acid encoding a polypeptide having at least 95% homology to SEQ ID NO: 2 and transformed into any nonhuman organism, and cloned into a vector further comprising a multitude of other genes; it would require undue experimentation to make and/or use the invention, as broadly claimed.

8. Applicants' arguments filed August 13, 2008 have been fully considered but they are not persuasive. Applicants argue that the delta-4 desaturase sequence may be modified or cloned using methods disclosed in the specification. The Examiner maintains that applicants are arguing limitations that are not in the claims in that the claims no longer recite delta-4 desaturase activity, with the exception of new dependent claim 21. The amendment of claim 1 to recite that the isolated nucleic acid coding for a polypeptide having 95% homology with SEQ ID NO: 4 and having delta-4 desaturase activity would overcome the rejection for claims 1-3 and 5-8. However, without the recitation of delta-4 desaturase activity, one skilled in the art would not know what activity to screen for among the genus of sequences that are encompassed by the claims.

9. Applicants further argue that the enablement requirement is met as long as one method for making and using the claimed invention is provided that bears a reasonable correlation to the entire scope of the claim with regard to the nucleic acid sequence, gene construct and vector. The Examiner maintains the rejection given that the claims are drawn to a genus of sequences that encode a polypeptide that is at least 95% homologous to SEQ ID NO: 2. However, no functional activity is specified. The specification is only enabling for the claims drawn to nucleic sequence, gene construct and vector to the extent they are drawn to a nucleic acid encoding SEQ ID NO: 2 or to a sequence that encodes a polypeptide that is 95% homologous to SEQ ID NO: 2 that has delta-4 desaturase activity. The specification does not disclose other uses for the claimed nucleic acids.

10. In addition, applicants argue that the specification provides working examples on how to generate a nonhuman organism, such as a yeast or plant that expresses a delta-4 desaturase.

Applicants argue that sufficient guidance is provided for producing nonhuman transgenic organisms, and one skilled in the art would expect to produce polyunsaturated fatty acids in a nonhuman transgenic organism that expresses the delta-4 desaturase when DPA is exogenously supplied or is produced by the organism. The Examiner maintains that guidance in the specification for the production of transgenic yeast and plants does not support enablement for any nonhuman organism. The specification does not provide guidance on how to make and/or use transgenic organisms in the animal kingdom, which encompasses a wide range of organisms including worms, sponges, insects, mollusks, fish, birds, reptiles and mammals, to name a few.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claims are allowed.

13. Claim 21 is objected to for depending on a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EFM

/Elizabeth F. McElwain/
Primary Examiner, Art Unit 1638